Date: XX.XX.XXXX

Olympus reference: QIL FY26-EMEA-29- FY26-073 Detachment of Distal Tip Components on THUNDERBEAT II Devices

URGENT FIELD SAFETY NOTICE/ PRODUCT REMOVAL

RE: THUNDERBEAT™ II Shears with Ultrasonic Mode

Attention: Operating Room / Surgery and Risk Management Departments

Material ID	Model Number	Material Description	Lot Numbers	UDI-DI
R5001008	TB2-0520FC	5-mm x 20-cm THUNDERBEAT II Shears with Ultrasonic Mode	All	04953170439995
R5001009	TB2-0525FC	5-mm x 25-cm THUNDERBEAT II Shears with Ultrasonic Mode		04953170440007
R5001010	TB2-0535FC	5-mm x 35-cm THUNDERBEAT II Shears with Ultrasonic Mode		04953170440014
R5001011	TB2-0545FC	5-mm x 45-cm THUNDERBEAT II Shears with Ultrasonic Mode		04953170440021

Dear HealthCare Provider:

This letter is to inform you that Olympus is initiating a Field Corrective Action for the THUNDERBEAT II (Figure 1) models listed in this letter. These devices are intended to be used for open, laparoscopic, and endoscopic surgery to cut, seal, coagulate, grasp, and dissect. This action is being taken due to multiple reports of detachment of a distal tip component of the device during use.

You must immediately cease usage of all THUNDERBEAT II devices and quarantine the product.

Figure 1. Image of a THUNDERBEAT II device

Reason for Action:

From their initial commercial release in October 2025 through December 2025, Olympus received four complaints as follows (see Figure 2 for a depiction of the various components at the distal end of THUNDERBEAT II devices):

- One instance involved detachment of the probe outside of the patient after the device was removed.
- Two instances involved detachment of the pad holder cover (which may also be known as the resin cover or the thermal shield) within the patient requiring retrieval, one of which also reported charring of the tissue pad. One additional instance of detachment of the pad holder cover occurred outside of the patient after the device was removed.

None of the four complaints reported any further injury to the patient.

An investigation by Olympus has determined that some distal tip components can experience thermal damage from use involving activation without tissue present between the grasping jaw and the probe (which can occur if tissue is not grasped prior to activation or if activation is continued after the tissue has been cut). This thermal damage can make the components more susceptible to detachment during use. Due to the likelihood of continued occurrence of this issue with device use and the associated risk to health (see the following section), Olympus is removing all models of THUNDERBEAT II devices from the market.

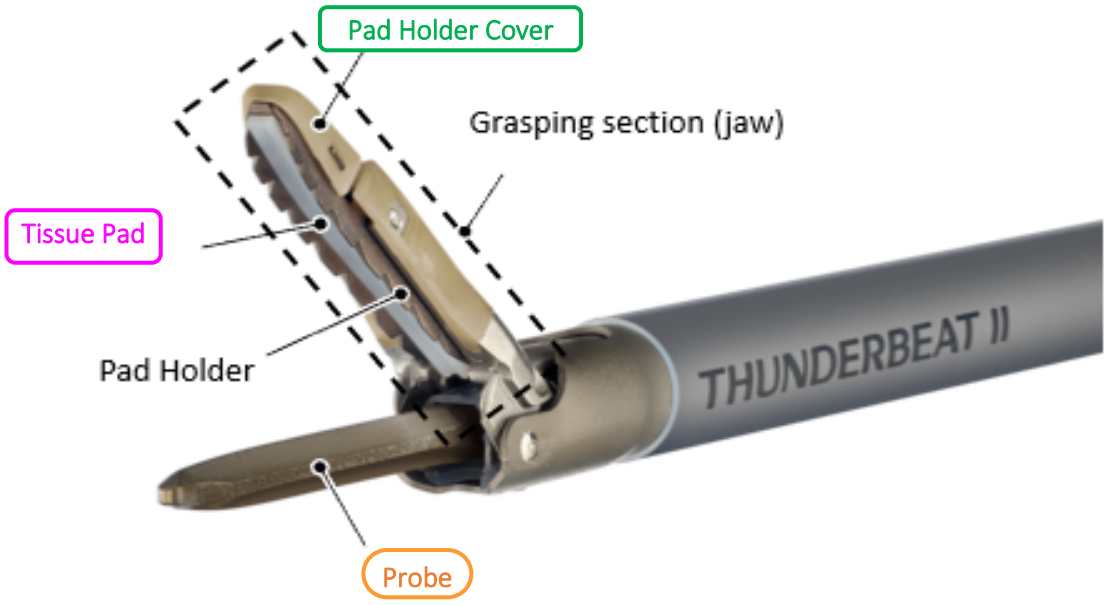

Figure 2. Image showing the pad holder cover, tissue pad, and probe components at the distal end of the THUNDERBEAT II devices.

Risk to Health:

A broken probe tip, pad holder cover, or a damaged tissue pad may lead to various patient harms. Of these harms, the most common harm is a foreign body in the patient due to a probe tip, pad holder cover, and/or tissue pad that becomes damaged and breaks off the device during use. When this occurs, it can also potentially result in prolonged operative time, the requirement to perform imaging examinations, or an additional surgical procedure to locate and remove the broken device fragment. In rare circumstances, tissue damage could occur due to exposed sharp edges on the device when the device tip breaks or becomes damaged. Additionally, bleeding may occur if the tissue pad fails or probe breaks, causing an inadequate seal. Post-operative bleeding events could, in rare circumstances, result in life-threatening injuries.

The potential harms of burn(s), granuloma, and inflammatory reaction may also result due to a broken probe tip, pad holder cover, or tissue pad that is not immediately retrieved and/or is unretrievable. While not seen in the complaint data, these harms may occur on rare occasions. The potential harm of burn(s) may occur due to retained heat in the probe tip, pad holder cover, or tissue pad that potentially breaks off into a patient.

Actions Required:

Our records indicate that your facility has purchased one or more of the affected products. Olympus therefore requests that you take the following actions:

1. **Immediately cease usage of all THUNDERBEAT II devices.**
2. Examine your inventory for the model numbers / UDI numbers listed in the table on page 1 of this notice and quarantine any affected products.
3. Olympus requests that you acknowledge receipt of this FSN. **Note:** This request applies even if you no longer have any affected product in your inventory.
4. If you have affected products in your inventory, please contact Olympus with regard to return of affected products. Olympus will issue a credit to your facility upon return of your affected product
5. If you have further distributed it, forward this notice to other users who may have affected products.

[If applicable:] Your National Competent Authority is aware of the actions described in this letter.

Olympus requests that you report any complaints, including distal tip component detachment to [local facility complaint reporting contact]. [If applicable:] Adverse events experienced with the use of this product may also be reported [local competent authority] by [method].

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact [me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].

Sincerely,
Name
Olympus title

REPLY FORM

QIL FY26-EMEA-29- FY26-073 Detachment of Distal Tip Components on THUNDERBEAT II Devices

Facility name	
Facility Address	
Contact Name	
Contact E-mail Address	
Contact Telephone Number	

Insert description of the product names, lot numbers and quantity of the affected products remaining in your facility

Catalogue Number	Lot Number	Quantity

I acknowledge receipt of this notification. I confirm that I have further communicated to any affected departments.

Completed By:		
		Click or tap to enter a date.
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to XXX by date XXX.